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10/508,958	12/12/2005	Yoshinori Naoe	259908US0XPCT	7546

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	**PAPER NUMBER**
1627	

NOTIFICATION DATE	DELIVERY MODE
09/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/508,958	NAOE ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11 and 16-20* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of July 14, 2010 made to the office action filed March 17, 2010. Claims 1-5, 7-11 and 16-20 are pending. Claims 8-11 and 16-20 are withdrawn from consideration. Claims 1, 4 and 7 are amended.

The provisional obviousness-type double patenting rejections over U.S. Patent Application No. 10/486,833 US Application No. 11/064,292 and US patent No. 7,314,862 are maintained being that the Applicant's arguments are not persuasive and terminal disclaimers have not as-yet been filed.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 1-5 and 7 as being unpatentable over Nakajima et al., in view of Georges et al., in further view of Ueda et al. were found not persuasive, thus the rejection is upheld.

Due to the Applicant's amendments to the claims, the modified rejections are below. The Applicant's arguments are addressed below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 1-5 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48, 50 and 55 of copending Application No. 11/064,292 ('292) in view of Georges et al (US 2002/0065282 A1) in further view of Ueda et al. (The Journal of Antibiotics, 1994, vol. 43(3), page 301-310). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '292 teaches a method of treating tumor patient who has kidney cancer comprising administering to a patient the compound of formula (I) (see claims 48 and 55) or FK 228 (i.e. the stereoisomer of formula (I); current applications compound of formula (II); see claim 54) and docetaxel. For clarification, the specification discloses that a patient is a human and administration intravenously (i.e. *in vivo*; see page 17, lines 15-20).

The application '292 does not specifically disclose the suppression of a cancerous tumor in the kidney nor to a mammal in need.

Georges et al. teaches a method of treating the proliferation of malignant cell and cancer of the breast, lung, colon, rectum, stomach, prostate, bladder, pancreas, ovary as well as solid tumors of the kidney, liver, prostate and pancreas with a histone deacetylase inhibitor (see page 3, paragraph 36, lines 8-10, 18 and 19) to a human in need of treatment (see paragraphs 36 and 38).

Ueda et al. teaches the applicants compound of formula I and II as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the patent '862 and the suppression of a cancerous tumor in the kidney because kidney cancer is treated by '862. Further one would be motivated to treat kidney cancer with the compound of formula I without docetaxel because the compound of formula I is known to treat cancer by being a histone deacetylase inhibitor (see Ueda et al.). Further, histone deacetylase inhibitors are suspected to treat kidney cancer as taught by Georges et al.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the application '292 and the suppression of a cancerous tumor in the kidney in a mammal in need because kidney cancer is treated by the application '292 (see claim 55). Further one would be motivated to treat kidney cancer with the compound of formula I without doxorubicin because the compound of formula I is known to treat cancer by being a histone deacetylase inhibitor (see Ueda et al.). Additionally, histone deacetylase inhibitors are suspected to treat kidney cancer as taught by Georges et al. Lastly, since docetaxel is a known antitumor agent it is obvious to combine two antitumor agents to treat tumors. Thus, it would be obvious to administer the compound of formula I to a mammal in need because '292 teaches treating kidney cancer by administration to a human and therefore is in need of treatment. Additionally, Georges et al. teaches that histone deacetylase inhibitors are administered to a human in need of treatment (see paragraphs 36 and 38).

(2) Claims 1-5 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-13 of Patent No. US 7,314,862 B2 ('862) in view of Georges et al (US 2002/0065282 A1) in further view of Ueda et al. (The Journal of Antibiotics, 1994, vol. 43(3), page 301-310). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The patent '862 teach a method of treating cancer or a tumor of the kidney comprising administering to a subject in need an effective amount of the compound of formula (I) (see claims 11-13 and 69) or FK 228 (i.e. the stereoisomer of formula (I); current applications compound of formula (II); see claim 13) and doxorubicin. The method is administered orally, parenterally, intranasally, pulmonarily, vaginally, or transrectally (i.e. *in vivo*; see claims 18 and 19). For clarification, the specification discloses that a subject is a human (see column 9, lines 44-49).

The patent '862 does not specifically disclose the suppression of a cancerous tumor in the kidney.

Georges et al. teaches a method of treating the proliferation of malignant cell and cancer of the breast, lung, colon, rectum, stomach, prostate, bladder, pancreas, ovary as well as solid tumors of the kidney, liver, prostate and pancreas with a histone deacetylase inhibitor (see page 3, paragraph 36, lines 8-10, 18 and 19).

Ueda et al. teaches the applicants compound of formula I and II as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the patent '862 and the suppression of a cancerous tumor in the kidney of a mammal because kidney cancer is treated by '862. Further one would be motivated to treat kidney cancer with the compound of formula I without doxorubicin because the compound of formula I is known to treat cancer by being a histone deacetylase inhibitor (see Ueda et al.). Additionally, histone deacetylase inhibitors are suspected to treat kidney cancer as taught by Georges et al. Lastly, since doxorubicin is a known antitumor agent it is obvious to combine two antitumor agents to treat tumors. Lastly, Ueda et al. teach that the compounds of formula I and II as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2), thus it would be obvious to treat mammals.

(3) Claims 1-5 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 60 of copending Application No. 10/486,833 ('833) in view of Georges et al (US

2002/0065282 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '833 teaches a method of treating prostate cancer comprising administering an effective amount of the compound of formula (I) (see claim 45) or a compound of formula (II) (see claim 60). For clarification, the specification discloses that the method is administered to a human intravenously, intramuscularly or orally (see page 11, lines 16 and 17).

The application '833 does not a treatment for kidney cancer or the suppression of a cancerous tumor in the kidney in a mammal in need.

Georges et al. teaches a method of treating the proliferation of malignant cell and cancer of the prostate as well as solid tumors of the kidney with a histone deacetylase inhibitor (see page 3, paragraph 36, lines 8-10, 18 and 19) to a human in need of treatment (see paragraphs 36 and 38).

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To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the application '833 and the treatment of kidney cancer to a mammal in need because Georges et al. teaches that histone deacetylase inhibitors treats prostate and kidney cancer in a human in need of treatment (see paragraphs 36 and 38). Since the applicant's compound is a histone deacetylase inhibitor, then by the same mechanism, the compound will also treat kidney cancer and suppress cancerous tumors in the kidney.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al. (Experimental cell research, 1998, 24, pages 126-133) in view of Georges et al (US 2002/0065282 A1) in further view of Ueda et al. (The Journal of Antibiotics, 1994, vol. 43(3), page 301-310).

Nakajima et al. teaches the compound of formula I and II as an inhibitor of intracellular histone deacetylase activity (see title, abstract, lines 15 and16, and page 127, figure 1) that strongly inhibits proliferation of tumor cells *in vitro* and greatly suppresses the growth of transplanted tumors in mice (i.e. mammal in need; see page 126, column 2, last 4 lines; addresses claims 1-5).

Nakajima et al. does not teach a treatment for kidney cancer or the suppression of a cancerous tumor in the kidney. Nakajima et al. also does not specifically teach the applicant's compound *in vivo* or in a human.

Georges et al. teaches a method of treating the proliferation of malignant cell and cancer of the breast, lung, colon, rectum, stomach, prostate, bladder, pancreas, ovary as well as solid tumors of the kidney, liver, prostate and pancreas with a histone deacetylase inhibitor (see page 3, paragraph 36, lines 8-10, 18 and 19) to a human in need of treatment (see paragraphs 36 and 38).

Ueda et al. teaches the applicants compound of formula I and II as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine Nakajima et al. and the treatment of kidney cancer because Georges et al. teaches that histone deacetylase inhibitors treats prostate and kidney cancer. Since the applicant's compound is a histone deacetylase inhibitor, then by the same mechanism, the compound will also treat kidney cancer and suppress cancerous tumors in the kidney. Additionally, without unexpected results, one skilled in the art would reasonably expect that an anti-tumor drug would treat a tumor in the kidney.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine Nakajima et al. and suppressing the growth of cancerous tumors of the kidney *in vivo* in a human because Ueda et al. teaches the applicant's compounds as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2). Thus, it would be obvious to administer the compound of formula I to a mammal in need because Georges et al. teaches that histone deacetylase inhibitors are administered to a human in need of treatment of cancers such as kidney cancer (see paragraphs 36 and 38).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that Georges et al. provides nothing more than mere speculation of an unsupported "expectation" that their compounds would work for treating virtually any form of cancer. At no point do Georges et al. disclose, suggest or offer supportive data that HDAC inhibitor suppresses kidney cancer nor does Georges et al. provide any reference citation that discloses the same. Particularly, Marks et al., which is cited by Georges et al. test plural HDAC inhibitors in animal models for the suppression of proliferation of tumors in breast, prostate, and lung. However, no report refers to kidney cancer. Further, the skilled artisan would appreciate that sensitivity to anti-tumor agents varies depending on the type of cancer, and the type of cancer that proves effective should be ascertained by panel tests and the like. Since no other HDAC inhibitors have exhibited an effect for kidney cancer, there is no motivation to apply the HDAC inhibitor to kidney cancer. The state of the art demonstrates that there is no direct expectation of in vivo efficacy from the in vitro observation of HDAC inhibitory activity. There is no expectation of success, thus it would not be obvious to try.

The Examiner disagrees again because Georges et al. provides the motivation to try other HDAC inhibitors to treat other cancers, such as kidney cancer (see page 3, paragraph 36). The expectation of success is that a mechanism of action has been established between HDAC inhibitors and several cancers. In KSR, the Supreme Court rejected the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, stating that "The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and

other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." KSRInt'l v. Teleflexlnc., 127 S. Ct. 1727, 1740 (2007). Applying the KSR standard of obviousness to the findings of fact, it would have been obvious to apply the method of the Georges et al. with the compounds of Nakajima et al. and Ueda et al. because of the following reasons: 1) both the references teach the applicant's compounds as an anti-tumor agent; 2) Nakajima et al. teach that the applicant's compound has the same mode of action as Georges et al.; and 3) Ueda et al. specifically teach that applicant's compounds as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2). Therefore, although Georges et al. and the references cited within do not teach the treatment of kidney cancer with an HDAC inhibitor, one skilled in the art would be motivated to try compounds with this mechanism of action with the expectation of treatment for kidney cancer as taught by Georges et al. In regards to expectation of success for *in vivo* efficacy based on *in vivo* data, the prior art demonstrates that *in vitro* data does relate to efficacy *in vivo* for other cancers treated with HDAC inhibitors, as taught by Ueda et al.

> Applicants further argue that cell lines used in the *in vitro* study of Ueda et al. are human lung and mammary adenocarcinoma. Additionally the cells were transplanted under the kidney capsule of the BDF1 mice. Thus, none of these experiments provide any suggestion to treat kidney cancer or any expectation of the efficacy when so doing. Just because a breast cancer cell is grown on the kidney does not instantly make it "kidney cancer". Therefore, it will be understood that the SRC Assay of Ueda et al. is a sensitivity test for rapid evaluation of a clinical affect of an

> anticancer drug for various tumors as demonstrated by Nishimura et al., Gan and Bogden et al. Particularly, Nishimura et al. demonstrate that FR900840 failed to show activity in some tumors, which suggest that the activity of a compound against a tumor cannot be predicted based only on an *in vivo* activity of the compound against a different kind of tumor.

The Examiner again disagrees because the prior art provides motivation and reasonable expectation of success to try the applicants compounds to treat kidney cancer. Particularly, *in vivo* treatment of kidney cancer is obvious because of the following reasons: 1) George et al. has demonstrated treating the proliferation of malignant cells with HDAC inhibitors (see page 3, paragraph 36); 2) Nakajima et al. teaches that the applicant's compounds are HDAC inhibitors; and 3) Ueda et al. teaches that the applicant's compounds are anti-tumor agents against human tumor cell lines both *in vitro* and *in vivo* (see page abstract lines 1, 4 and 5, and page 302, figure 2). Thus, one skilled in the art would not have reasonable expectation that the applicant's compounds can be administered to humans to treat kidney cancer. Since George et al. teaches that HDAC inhibitors are expected to treat kidney cancer, one of ordinary skill in the art would have motivation to try HDAC inhibitors to treat cancer since it is already effective in treating the proliferation of malignant cells and other cancers. In regards to Nishimura et al., It would be irresponsible to think that the compound would magically treat all forms of cancer/tumors, but because of the reasons above, the prior art references provide an obviousness reason to try.

Obvious Double Patenting Rejections

> The Applicant argues that current invention has an earlier effective filing date than US 11/064,292 and US 7,314,862. Further, the Examiner has not properly rejected the claims by using a two-way obviousness determination. Additionally, the claims in US 7,314,862 require a compound of formula I and doxorubicin to treat kidney cancer. None of the claims suggest that the compound of formula I can treat kidney cancer alone. In regards to co-pending application No. 10/486,833, Georges et al. does not compensate for the deficiency of the application not treating kidney cancer for reasons given in the 35 U.S.C. 103(a) rejection arguments. Additionally, the amendments to the claims should be further reason for the rejection to be withdrawn.

The Examiner disagrees because the modified rejections address the "in need thereof" language in the amended claims. As stated in the previous action, one would be motivated to treat kidney cancer with the compound of formula I without doxorubicin or docetaxel because the compound of formula I is known to treat cancer by being a histone deacetylase inhibitor (see Ueda et al.). Additionally, histone deacetylase inhibitors are suspected to treat kidney cancer as taught by Georges et al. Lastly, since doxorubicin and docetaxel are known antitumor agents it is obvious to combine two antitumor agents to treat tumors. In regards to co-pending application No. 10/486,833, the Examiner upholds the arguments of Georges et al. as stated above in the 35 U.S.C. 103(a) rejection response. In regards to the rejections being made using a two-way obviousness, the Examiner disagrees that a two-way obviousness argument needs to be made. Although the examined application has an effective filing date before the conflicting patent (US 7,314,862), there is no sufficient evidence that there was administrative delay on the part of the Office in the application being examined. The Examiner has examined the Applicant's claims and addressed the Applicant's arguments in each phase of examination. The Applicant's have amended the claims to

overcome the Examiner's rejections, and the Examiner has modified or used new rejections to address the new claim limitations. Thus, there has been no evidence of administrative delay on the part of the Office. Therefore, a one-way obviousness type rejection is appropriate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kendra D Carter/
Examiner, Art Unit 1627

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627